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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/067,148	05/26/93	MONTAGNIER L	3495.000404

HM11/0303

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EXAMINER	
PARKIN,J	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/03/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

☆U.S.GOVERNMENT PRINTING OFFICE 1995-319-826

Office Action Summary	Application No. 08/067,148	Applicant(s) Montagnier et al.
	Examiner Jeffrey S. Parkin, Ph.D.	Group Art Unit 1648

☒ Responsive to communication(s) filed on *23 Oct 1997* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *15, 16, 18-20, and 29-31* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *15, 16, 18-20, and 29-31* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Detailed Office Action

Status of the Claims

1. Acknowledgement is hereby made of the communication filed 23 October, 1997. In response to this communication, Applicants are hereby advised that the finality of the rejection in the last Office action is withdrawn. Claims 15, 16, 18, 19, 20, 29, 30, and 31 are pending in the instant application.

35 U.S.C. § 112, First Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 15, 16, 18-20, and 29-31 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Claims 15, 16, and 18-20 are directed toward antibodies specific toward HIV-1 p12, p18, mixtures of antibodies specific for p12 and p25, mixtures of antibodies specific for p18 and p25, and mixtures of antibodies specific for p12, p15, p18, p25, p36, p42, and p80. Claims 29-31 are drawn toward immunological complexes comprising a purified HIV-1 antigen (e.g., p12 or p18) and specific antibody.

The written description requirement under Section 112, first paragraph, stipulates that the claimed subject matter must be supported by an adequate written description that is sufficient to

enable anyone skilled in the art to make and use the invention. The courts have decided that the specification must demonstrate that the inventor had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, nonetheless, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *Ralston Purina Company* v. *Far-Mar-Co., Inc.*, 227 U.S.P.Q. 177 (C.A.F.C. 1985). *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Wertheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Blaser, Germscheid,* and *Worms,* 194 U.S.P.Q. 122 (C.C.P.A. 1977). *In re Driscoll*, 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter* v. *Hiraga*, 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988).

This rejection is based upon the inability of the disclosure to reasonably convey to the skilled artisan that applicants were in possession of the claimed HIV-1 antibodies and immunological complexes at the time of the filing date relied upon. The specification fails to provide any demonstrative evidence that applicants had generated the claimed antibodies or immune complexes. Moreover, the disclosure only refers to subject matter directed toward a newly isolated virus, the antigens p13, p18, and p25 (refer to disclosure, page 6). The disclosure describes the isolation, purification, and propagation of this virus, designated LAV by applicants. It was further reported that extracts containing p12, p18, and/or p25 were prepared. There was one mention of patient antibodies that displayed reactivity toward the LAV antigens p12, p18, p25, p36, p42, and p80 (refer to page 13 of the disclosure). However, there was no indication that applicants actually contemplated generating, isolating, and characterizing LAV-specific antibodies. Moreover, there is no indication that applicants actually contemplated making and/or using these antibodies or immune complexes comprising these antibodies and the appropriate viral antigen. Accordingly, the skilled artisan would reasonably conclude

that applicants were not in possession of the claimed invention at the time of filing. Applicants may obviate the rejection by providing scientific evidence demonstrating that the claimed antibodies and immune complexes were actually generated.

Non-statutory Double Patenting

4. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969); *In re Vogel,* 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); *In re Van Ornum,* 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Longi,* 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); and *In re Goodman,* 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

5. Claims 18-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 10-13, and 18-22 (refer to Appendix A) of U.S. Patent No. 5,135,864. The claims of the '864 patent disclose the HIV-1 antigens p15, p25, p36, p42, and p80. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to generate antibodies against these proteins to facilitate the

detection of HIV-1. One of ordinary skill in the art would be motivated to use these antibodies either alone, or in combination, for diagnostic purposes.

6. Claims 15, 16, 18, and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5, 7, and 9-11 (refer to Appendix A) of U.S. Patent No. 5,217,861. The claims of the '861 patent disclose the HIV-1 antigens p12, p18, and p25. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to generate antibodies against these proteins to facilitate the detection of HIV-1. One of ordinary skill in the art would be motivated to use these antibodies either alone, or in combination, for diagnostic purposes.

Correspondence

7. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

8. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 305-7939. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

9. Any inquiry concerning this communication should be directed to **Jeffrey S. Parkin, Ph.D.**, whose telephone number is **(703) 308-2227.** The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, **Donald E. Adams, Ph.D.**, can be reached at **(703) 308-0570.** Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600

receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

28 February, 1998

LAURIE SCHEINER
PRIMARY EXAMINER

Appendix A

92:63788 Human Immunodeficiency Virus (HIV) associated with Acquired Immunual Deficiency Syndrome (AIDS), a diagnostic method for aids and pre-aids, and a kit therefor.
Montagnier, Luc, Le Plessis Robinson, France
Chermann, Jean-Claude, Elancourt, France
Barre-Sinoussi, Francoise, Issy Les Moulineaux, France
Brun-Vezinet, Francoise, Paris, France
Rouzioux, Christine, Paris, France
Rozenbaum, Willy, Paris, France
Dauguet, Charles, Paris, France
Gruest, Jacqueline, L'Hay Les Roses, France
Nugeyre, Marie-Therese, Paris, France
Rey, Francoise, Paris, France
Axler-Blin, Claudine, Paris, France
Chamaret, Solange, Paris, France
Gallo, Robert C., Bethesda, MD, United States
Popovic, Mikulas, Bethesda, MD, United States
Sarngadharan, Mangalasseril G., Vienna, VA, United States
Institut Pasteur, Paris Cedex, France (non-U.S. corporation)The United States of America as represented by the Secretary of The Department of Health and Human Services, Washington, DC, United States (U.S. government)
US 5135864 920804
APPLICATION: US 87-117937 871105 (7)
DOCUMENT TYPE: Utility.
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
CLM What is claimed is:

6. An antigen of said mixture as claimed in claim 5, wherein said protein is p25 protein of HIV.

10. A structural protein of said mixture as claimed in claim 7, wherein said protein is p15 protein of HIV.

11. A structural protein of said mixture as claimed in claim 7, wherein said protein is p36 protein of HIV.

12. A structural protein of said mixture as claimed in claim 7, wherein said protein is p42 protein of HIV.

13. A structural protein of said mixture as claimed in claim 7, wherein said protein is p80 protein of HIV.

18. Retroviral extract as claimed in claim 17, wherein said extract comprises p25 protein of said retrovirus.

19. Retroviral extract as claimed in claim 17, wherein said extract comprises p15 protein of said retrovirus.

20. Retroviral extract as claimed in claim 17, wherein said extract comprises p25 protein of said retrovirus.

21. Retroviral extract as claimed in claim 17, wherein said extract comprises p36 protein of said retrovirus.

22. Retroviral extract as claimed in claim 17, wherein said extract comprises p80 protein of said retrovirus.

L1 ANSWER 24 OF 42 USPATFULL
93:46308 Antigen of a human retrovirus, namely p18 protein of human immunodeficiency virus (HIV), compositions containing the antigen, a diagnostic method for detecting acquired immune deficiency syndrome (AIDS) and pre-AIDS and a kit therefor.
Montagnier, Luc, Le Plessis-Robinson, France
Chermann, Jean-Claude, Elancourt, France
Barre-Sinoussi, Francoise, Issy les Moulineaux, France
Vezinet-Brun, Francoise, Paris, France
Rouzioux, Christine, Paris, France
Rozenbaum, Willy, Paris, France
Dauguet, Charles, Paris, France
Gruest, Jacqueline, L'Hay les Roses, France
Nugeyre, Marie-Theresa, Paris, France
Rey, Francoise, Paris, France
Axler-Blin, Claudine, Paris, France
Chamaret, Solange, Paris, France
Institut Pasteur, France (non-U.S. corporation)
US 5217861 930608
APPLICATION: US 88-158073 880212 (7)
PRIORITY: GB 83-24800 830915
ZA 84-7005 840916
DOCUMENT TYPE: Utility.
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
CLM What is claimed is:

4. Structural protein of Human Immunodeficiency Virus (HIV), which is p18 protein of said virus, and said protein is in isolated form.

5. A labeled polypeptide, wherein the polypeptide is capable of being immunologically recognized by serum of a patient afflicted with Lymphadenopathy Syndrome (LAS) or Acquired Immune Deficiency Syndrome (AIDS); the polypeptide is p18 protein of Human Immunodeficiency Virus (HIV) in isolated form; and said label is an immunoassay label selected from the group consisting of a radioactive label, an enzyme label, and a fluorescent label.

7. An isolated mixture of structural proteins of Human Immunodeficiency Virus (HIV), wherein the proteins are p18 and p25 proteins.

9. Structural protein of Human Immunodeficiency Virus (HIV), which is p12 protein of said virus, and said protein is in isolated form.

10. A labeled polypeptide, wherein the polypeptide is capable of being immunologically recognized by antibodies in the serum of a patient afflicted with Lymphadenopathy Syndrome (LAS) or Acquired Immune Deficiency Syndrome (AIDS); the polypeptide is p12 protein of Human Immunodeficiency Virus (HIV) in isolated form; and said label is an immunoassay label selected from the group consisting of a radioactive label, an enzyme label, and a fluorescent label.

11. A mixture of structural proteins of Human Immunodeficiency Virus (HIV), wherein the proteins are selected from the group consisting of p12, p18, and p25 proteins, and the mixture is in isolated form.